Fear of black market means no RU-486 for Canada until US approves drug

Barbara Sibbald

In brief

Mifepristone, the "abortion pill" that is better known as RU-486, is no closer to arriving in Canada than it was 8 years ago. But that fact hasn't slowed debate about the product.

anufacturers of a controversial "abortion pill" won't even apply for Canadian approval until after doctors in the US start prescribing the drug. Exelgyn, the French manufacturers of mifepristone (RU-486), say they won't even apply in Canada until after US approval because of the "risk of a black market between the countries."

In an interview from Paris, Exelgyn spokesperson Catherine Euvrard said "it's out of our hands." The US manufacturer of mifepristone expects to have full approval by next year.

But BC Health Minister Penny Priddy is optimistic that Exelgyn will apply for Canadian approval before that, especially now that it has all the application information. "I think Exelgyn is going to file an application soon," she said in a phone interview.

The Society of Obstetricians and Gynaecologists of Canada (SOGC) isn't holding its breath, though. In 1992 it passed a resolution supporting the "legal availability" of antiprogesterone steroids such as mifepristone in order to give "Canadian women access to a treatment of proven efficacy." But after 2 years, it decided "not to pursue the matter any more." Dr. André Lalonde, the executive vice-president, says new antiprogestins are arriving that may be superior to mifepristone, and the SOGC is now concentrating on lobbying to have emergency contraception available to women without a prescription. "They could reduce by two-thirds the need for abortions," says Lalonde. Guidelines are expected in mid-August.

But after 8 years of lobbying for mifepristone, BC's New Democratic Party government refuses to give up on the drug. Its ministry of health is concerned about women's right to choice and about violence against abortion providers and, in some cases, patients and their relatives. They argue that the use of RU-486 may reduce or eliminate many of these concerns.

Priddy says physicians and registered nurses are receiving hate mail, threats and harassing phone calls from peo-

ple who oppose abortion. Late in 1998, a BC hospital was evacuated during an abortion-related bomb scare.

Three Canadian physicians — including one from Vancouver — who provide abortions have been wounded in sniper attacks at their homes (see sidebar). And last fall, gynecologist Barnett Slepian of Buffalo was shot and killed by a sniper. "This terrorism has the potential to prevent women from getting medical services," says Priddy. A prescription is confidential and one way to provide service that is safe and accessible, she adds.

Not everyone shares her feelings. The Catholic Organization for Life and Family (COLF) "objects strongly to the introduction of mifepristone" because it "destroys life" and poses a "serious health risk to the mother." COLF has twice written to the federal minister of health stating that the drug "deeply offend[s] the consciences and religious sensibilities of millions of Canadians."

Jennifer Leddy, legal and policy advisor for the Canadian Conference of Catholic Bishops, says approval of mifepristone would set a legal precedent. She says that abortion now exists in a legal "vacuum" — there's no law against it, but there's no legal right to an abortion either. Approval of mifepristone "would be taking an active step in favour of an active method of abortion, which is further than [the government] has gone to date."

Planned Parenthood, on the other hand, supports the need to give women a choice of methods. Executive director Bonnie Johnson says the delays are "insane. It's all because of the antichoice movement."

Political minefield

Priddy agrees that mifepristone is a political minefield, "but sometimes you have to walk in anyway, and this is one of those cases."

The pill allows women to have an abortion by prescription drug rather than by surgery. Used during the first 9 weeks of pregnancy, mifepristone causes a miscarriage by inducing uterine contractions. This allows women to have abortions at home. Clinical tests and use in Europe point to an effectiveness rate of more than 95%. Women take the drug at home and have 4 follow-up visits. Side effects include nausea and vomiting, pain and bleeding.

Due to the political controversy, Exelgyn will not apply for the drug's approval in any country until it is formally invited to do so by the government in question.



Mifepristone is now available in France, Britain, Sweden and China, and it is expected to be released in the US next year despite opposition from antiabortion groups. The drug was declared safe and effective by the US Food and Drug Administration in 1996, but final approval has been delayed pending details about its manufacture. Danco Group, the pharmaceutical firm with US rights to the drug, said mifepristone should be available in the US by next year.

In early 1998, Health Canada wrote to Exelgyn at the request of the BC government and explained how Canada's drug-approval system works. Priddy says this could be interpreted as an invitation. "They've been assured of a 'fair hearing,' that's enough for them to say 'we can do this' without a specific invitation," she says.

Under the Food and Drug Act, Health Canada cannot

ask a company to submit a drug for approval because it would give the perception of a bias in favour of the drug.

Leddy, meanwhile, says Health Canada is "going quite close to the line. They give the impression of encouraging and that's troubling because you can't help but wonder if there is a bias."

The Federation of Medical Women of Canada laments that the drug has become so politicized because it has other potential therapeutic applications that should be investigated. These include possible treatments for endometriosis, breast and brain cancer, and uterine fibroids. "The federation supports any research that gives women more health options," says the president, Dr. Charmaine Roye.

Barbara Sibbald is CMAJ's Associate Editor, News and Features.

Task force offers \$547 000 to solve shootings

The Canadian task force investigating sniper-style attacks on 3 Canadian physicians is offering a \$547 000 reward for help in solving the case. It may be the largest reward in Canadian history. And US police agencies have put up \$500 000 for information leading to the resolution of the murder of Dr. Barnett Slepian in Buffalo last October.

Theoretically, a single person could get more than \$1 million in reward money, says Canadian task force spokesman Inspector Keith McCaskill of the Winnipeg Police Service. "The task force believes the cases are likely linked. If that is solved, ours likely will be too, and if we solve in Canada it could solve the US case."

The Canadian task force has been working since September 1998 to set up a reward; it was finally posted March 19. "We're very appreciative of the fact that we got it," says McCaskill, adding that a reward is an important tool for solving this sort of case.

The reward money was put up by the RCMP, Ontario Provincial Police, Vancouver Police Department, Winnipeg Police Service, Hamilton–Wentworth Regional Police Service, the Canadian Abortion Rights Action League and unnamed public groups.

In all, 9 police forces on both sides of the border are investigating 5 incidents that are believed to be linked. All took place around Remembrance Day, all the

INFORMATION WANTED \$547,000.00 REWARD

NATIONAL TASK FORCE ON DOCTOR SHOOTINGS

Royal Canadian Mounted Police, Ontario Provincial Police,
Vancouver Police, Winnipeg Police,
Hamilton-Wentworth Regional Police Service,
Canadian Abortion Rights Action League & Other Public Institutions
HAVE JOINTLY OFFERED THIS REWARD FOR INFORMATION LEADING
TO THE ARREST AND CONVICTION OF THE PERSON OR PERSONS
RESPONSIBLE FOR THESE SHOOTINGS.



PERSON OF INTEREST ONLY James Charles KOPP DOB: 54 - 08 - 02 White Male, 44 years Height: 178 cm. 5'.8"

White Male, 44 years Height: 178 cm, 5' 8" Weight: 75 kg, 185 lbs. Brown Hair, Blue eyes

During the investigation, James Charles Kopp has been identified as a person of interest to the investigators.

A Canada wide warrant for the arrest of Kopp for violation of Canada's immigration laws is in effect.



physicians involved performed abortions and all were shot in their homes. The injured include Dr. Garson Romalis of Vancouver (1994), Dr. Hugh Short of Ancaster, Ont. (1995), an unnamed Richmond, NY, physician (1996) and Dr. Jack Fainman of Winnipeg (1997). The first fatality occurred last Oct. 23 when Slepian was shot and killed at his home.

An American murder warrant has been issued for Vermont antiabortion activist James Kopp, 44. Kopp, whose whereabouts are a mystery, is charged only in the slaying of Slepian. He remains a "person of interest" in connection with the other shootings.

Anyone with information can call the task force 877 687-3377 (toll free).